PHARMACY EXAMINING BOARD MADISON, WI MINUTES OCTOBER 15, 2003

PRESENT: Cynthia Benning, R.Ph.; Michael Bettiga, R.Ph.; John Bohlman, R.Ph.;

Georgina Forbes, Dan Luce, R.Ph.; Charlotte Rasmussen, Susan Sutter,

R.Ph.

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, Legal Counsel;

Pamela Meicher, Program Assistant; DOE Staff

GUESTS: Rhonda Leschisin, School of Pharmacy/Bohlman Drugstore; Franklin La

Dien, Walgreen Co.; Greg Primuth, Walgreen Co.; Elizabeth Nelson, Women's International Pharmacy; Susan Kleppin, UW Hospital & Clinics; Jamie Stat Paynter, Dean Pharmacy; Paul Baum, Group Health Cooperative; Tom Engels, Pharmacy Society of Wisconsin; Tony

Cooperative, Tom Engels, Pharmacy Society of Wisconsin, Tony

Driessen, Quaules & Brady LLP, Cardinal Health; Mickey Price, Cardinal

Health; Larry P. Edwards, Department of Corrections

CALL TO ORDER

Chair Susan Sutter called the meeting to order at 9:00 a.m. A quorum of 7 members was present.

AGENDA

Amendments to agenda:

Letter from Senator Judith Robson addressing the Canadian Drug Service store in Wauwatosa Department of Regulation and Licensing Monitor Report by Board

Article "Patient Appeals Judge for Canadian Drugs"

Letter from Mary S. Hayney, PharmD, BCPS addressing the live attenuated influenza vaccine

Letter from Aurora Pharmacy – temporary closing WI license #7749

Report of Manufacturer licenses granted August-October

Report of Distributor licenses granted August-October

Report of Pharmacist licenses granted August-October

Report of Total Pending Cases by Team and by Status

NAPB/AACP District IV Program Registration Materials

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, to approve the

agenda as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF SEPTEMBER 9, 2003

MOTION: John Bohlman moved, seconded by Cynthia Benning, to approve the minutes of September 9, 2003. Motion carried unanimously.

ADMINISTRATIVE REPORT

Tom Ryan reported that the Board Workshop held on October 14, 2003 was successful. Mr. Ryan also advised the Board that the 2004 meeting dates will be presented at the November meeting.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION

Chairperson Sutter's AB 355 Memorandum to Legislature

Chair Susan Sutter reviewed the communications she sent to the legislature summarizing the Board's concerns regarding this legislation.

LRB 2565/2

Chair Susan Sutter advised the Board she had spoken with Representative Wieckert's office regarding the Board's concerns covering the main points proposed in this legislation, as follows:

- If a prescriber writes the symptom or purpose as part of the directions for use for the drug on the prescription order, a pharmacist is already required to put that on the label.
- There was concern expressed about requiring prescribers and pharmacists in Wisconsin to adhere to another regulation that would not be applied to patients' prescriptions written by out-of-state physicians or filled by out-of-state pharmacies. The Board asks the legislature to be equally concerned for patients that access some of their healthcare outside of the state or country.
- Many prescriptions are not written but verbally given to the pharmacist by the prescriber or, more often, a delegated agent of the physician, and then reduced to writing. The Board was concerned that if a physician is accused of not abiding by the law in these instances, a debate could develop on who said what in the phone conversation. Many oral prescription orders are given to pharmacists by unlicensed personnel, i.e. a receptionist. The Board felt a "hold harmless" clause for the pharmacist in this situation was important to consider.
- The Board recommends that wording such as "consumer readability" or "plain language" be added to make certain that symptom or purpose for a drug would not be added just with ICD-9 codes, which would meet the letter of the law but not the intent of the law, which is to have the patient more informed.

MOTION: John Bohlman moved, seconded by Michael Bettiga, in favor of legislation in LRB 2565/2 short of the label requirement. Motion carried unanimously.

AB 560

Chair Sutter advised the Board the AB 560 (LRB 2697) language was changed relating to DEA rules. The legislation will not go into effect for a year after the physician Federal ID numbers are released. The Board favors physicians communicating diagnostic information to the pharmacists as long as that is the wish of the patient.

MOTION: John Bohlman moved, seconded by Cynthia Benning, in favor of Susan

Sutter sending a letter to legislators opposing legislation on AB 560.

Motion carried unanimously.

WIS. ADMIN. CODE § PHAR 7.05 – RECORDS MAINTENANCE – REVIEW AND REVISION

Mr. Black will revise the rule and present the revised rule at the November meeting.

PRESENTATION – REMOTE ACCESS SERVICE – "OFF-SITE ORDER ENTRY OF HOSPITAL MEDICATION ORDERS" – MICKEY PRICE, CARDINAL HEALTH

Mickey Price, Cardinal Health, delivered a presentation on an off-site order entry of hospital medication orders. The model is a pharmacy service center staffed with experienced hospital pharmacists who remotely access a hospital pharmacy system to review orders, perform prospective drug use review and approve orders within 60 minutes. The pharmacists are also available via toll free number to answer medication questions from medical and nursing staff. The model was created to fill a need for hospital pharmacies after closing hours.

Mr. Price wanted to know what steps Cardinal Health would have to take to work in Wisconsin. Based on the presentation and materials, Mr. Black did not think a variance would be required, however, the Pharmacists would need to be licensed in Wisconsin.

MOTION:

Dan Luce moved, seconded by Cynthia Benning, in favor of not requiring a variance for the model of Off-Site Order Entry of Hospital Medication Orders as presented by Mickey Price, Cardinal Health and that the pharmacist would need to be licensed in Wisconsin. Motion carried unanimously.

CANADIAN DRUG REIMPORTATION

The Board noted the letter from Governor Jim Doyle in support of legislation that will increase access to safe and affordable drugs for citizens in Wisconsin and the letter from Senator Judith Robson regarding the new Canada Drug Service store in Wauwatosa.

The Board has various concerns about Canadian Drug Reimportation and wants to ensure Wisconsin government is aware of their concerns. Some of the Board's concerns include where the drugs are manufactured, whether they are FDA approved, and drug integrity

MOTION: Charlotte Rasmussen moved, seconded by Dan Luce, in favor of

communicating with the Attorney General and all legislators their concerns around the reimporation of affordable prescription. Motion

carried unanimously.

MOTION: John Bohlman moved, seconded by Michael Bettiga, in favor of a

requirement that FDA approved drugs from Canada come through United

States pharmacies, not drug brokers. Motion carried unanimously.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, in favor of

writing a letter to Secretary Strong Hill requesting that unlicensed practice

cases be given the highest priority for resolution. Motion carried

unanimously.

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, in favor of

requesting that DOE open a case on unlicensed practice in Green Bay and

Wauwatosa (this can be advisory only). Motion carried unanimously.

COMPLIANCE QUESTION - STACY RICARD LAWLER, RPH - NEENAH, WI

The Board discussed a letter from Stacy Ricard Lawler regarding patient consultation on refills. Ms. Lawler suggested that pharmacists could use their time more efficiently with questions, dosing, interactions and new prescription consultations, and suggests refills for the pharmacist's services could be handled by a technician. Ms. Lawler stated that other states currently do not require consultation on refill prescriptions. Consultation on refills will be discussed further at the November meeting.

COMPLIANCE QUESTION - ATTORNEY CATHY BELLEHUMEUR - EAGAN, MN

Bill Black will advise Attorney Bellehumeur that this practice does comply with regulations.

REVIEW AND CONSIDERATION OF APPLICATION FOR APPROVAL – ACCUPAX, INC – FITCHBURG, WI

This issue was tabled until the November meeting.

COMPLIANCE QUESTION - SUSAN KLEPPIN, RPH

Attorney Bill Black will send a letter to Susan Kleppin advising her that if a pharmacy plans to administer vaccines, in any manner, it must have completed a course study and training covering vaccines.

MOTION: Dan Luce moved, seconded by Michael Bettiga, in favor of Susan Sutter

acting as the Board liaison for a statute change allowing pharmacists to

delegate to interns any administration of prescribed drug product or device

or vaccine, as long as the intern has successfully completed a course study of training. Motion carried unanimously.

BOARD DELEGATION DECISION RE: OUT OF STATE APPLICATIONS WITH A PAPER OR TECHNICAL ERROR

The Department has requested that they be allowed to approve and grant applications for distributors, manufacturers and pharmacies that have had a paper or technical error within another state. The Board would like to see process outlined by the Credentialing Division before a decision is made.

NABP SURVEY QUESTION RE: RE-PACKAGING – BOARD DECISION

The Department will respond to the survey and advise the NABP that Wisconsin does allow multiple lot numbers to be dispensed to the same cassette when using an automated dispensing machine.

NABP LEGISLATIVE CONFERENCE UPDATE - DAN LUCE

Dan Luce attended the conference. Mr. Luce will provide the Board with the USP criteria used when making their decision of not allowing repackaging of bubble packs.

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, in favor of the

Board joining the conference call with USP on repackaging. Motion

carried unanimously.

NABP REGIONAL CONFERENCE TRAVEL

Dan Luce will be attending the District meeting on his own and will not be representing the Board.

ELECTRONIC SIGNATURES

The Board reviewed Attorney Black's paper on electronic transmission of prescription orders and electronic signatures. Mr. Black will work with Chair Sutter to bullet point electronic signature items and request that the document be displayed on the Department website.

2004 MPJE TIME AND TASK SCHEDULE FOR PARTICIPATING BOARDS

The Board noted the 2004 MPJE Time and Task Schedule review and decided to send Bill Black to the state specific review meeting in Phoenix, AZ and to send Cynthia Benning to the item writing workshop in Rosemont, IL.

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, in favor of sending

Cynthia Benning to the MPJE Writing Workshop in Rosemont, IL,

January 9-11, 2004 and send Bill Black to the MPJE state specific review

meeting #1, January 23-25, 2004 in Phoenix/Scottsdale, AZ. Motion carried unanimously.

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, in favor of sending

Cynthia Benning to the MPJE Item-Writing Workshop, January 9-11,

2004 in Rosemont, IL. Motion carried unanimously.

INFORMATIONAL ITEMS

Dave O'Connell provided the Board with a Monitor Report by Board.

The Board advised Michael Berndt that a pharmacy located within another store does not need its own centrally located alarm system. Mr. Berndt will email inspection supervisor Greg Raube, asking him to inform his inspectors on this issue.

CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga to convene to

closed session to deliberate on cases following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation with administrative warning (Wis. Stat. § 19.85 (1) (b), and Wis. Stat. § 440.205); consider individual histories or disciplinary data (Wis. Stat § 19.85 (f)); and to confer with legal counsel (Wis. Stat § 19.85 (1) (g)). Motion carried by roll call vote: Cynthia Benning-yes, Michael Bettiga-yes, John Bohlman-yes, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan

Sutter-yes.

Open session recessed at 12:52 p.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Michael Bettiga, to reconvene

into Open Session at 2:35 p.m. Motion carried unanimously.

VOTING ON ITEMS DELIBERATED OR CONSIDERED IN CLOSED SESSION

APPROVAL OF EXAM SCORES

MOTION: Dan Luce moved, seconded by Cynthia Benning, to accept all the

examination scores as provided by the Examinations Office. Motion

carried unanimously.

REVIEW AND CONSIDERATION OF NAPLEX EQUIVALENCY – VINMANATHAN NAIDO – LAKE FOREST, IL

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to accept the

> California requirements as NAPLEX equivalent in the matter concerning Vinmanathan Naido, Lake Forest, IL. Motion carried unanimously.

REQUEST FOR REINSTATEMENT OF PHARMACIST LICENSE -**DELTON CHRISTENSEN – POCATELLO, ID**

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to require that

Delton Christensen take the NAPLEX, MPJE and practical exams.

Motion carried unanimously.

MARK ANDERSON - REQUEST FOR 3 MONTH STAY WITH MODIFICATIONS

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to grant a 3 month

stay of suspension in the matter of Mark Anderson, and deny his request

for modifications. Motion carried unanimously.

ROBERT GUZZETTA – REQUEST FOR 3 MONTH STAY

MOTION: Michael Bettiga moved, seconded by Cynthia Benning, to grant a 3 month

stay of suspension in the matter of Robert Guzzetta. Motion carried

unanimously.

KEVIN PAMPUCH - REQUEST FOR 3 MONTH STAY

MOTION: Cynthia Benning moved, seconded by Michael Bettiga, to grant a 3 month

stay of suspension in the matter of Kevin Pampuch. Motion carried

unanimously.

PRESENTATION OF CASE 02 PHM 069 FOR CONSIDERATION OF CLOSURE

MOTION: Michael Bettiga moved, seconded by Charlotte Rasmussen, to close case

02 PHM 069 for no violation. Motion carried unanimously.

PRESENTATION OF CASE 02 PHM 058 FOR CONSIDERATION OF CLOSURE

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to close case 02

PHM 058 for prosecutorial discretion. Dan Luce abstained. Motion

carried.

PRESENTATION OF CASE 02 PHM 093 FOR CONSIDERATION OF CLOSURE

MOTION: Dan Luce moved, seconded by Charlotte Rasmussen, to close case 02

PHM 093 for prosecutorial discretion. Roll call vote: Cynthia Benningyes, Michael Bettiga-no, John Bohlman-no, Georgina Forbes-yes, Dan Luce-yes, Charlotte Rasmussen-yes, Susan Sutter-no. Motion carried.

ADJOURNMENT

MOTION: Michael Bettiga moved, seconded by Georgina Forbes, to adjourn the

meeting at 2:35 p.m. Motion carried unanimously.

Next Meeting Wednesday, November 11, 2003